Rukobia (fostemsavir)
Policy Number: C20172-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DUE BY OR BEFORE
9/17/2020	11/4/2020	1/26/2022
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL/VERSION**
J8499	RxPA	Q1 2021 20210127C20172-A

PRODUCTS AFFECTED:
Rukobia (fostemsavir)

DRUG CLASS:
Antiretroviral Agents

ROUTE OF ADMINISTRATION:
Oral

PLACE OF SERVICE:
Specialty Pharmacy

AVAILABLE DOSAGE FORMS:
Rukobia 600mg (60 ct. bottle)

FDA-APPROVED USES:
Indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection, in combination with other antiretroviral(s), in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen

COMPENDIAL APPROVED OFF-LABELED USES:
None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS:
Multidrug resistant HIV-1 infection

REQUIRED MEDICAL INFORMATION:
A. MULTI-DRUG RESISTANT HIV1 INFECTION:

1. Documentation of a diagnosis of HIV and a baseline HIV RNA viral load of greater than≥ 400 copies/mL. [Documented within the past 30 days]
   AND
2. Prescriber attestation of member adherence to highly active antiretroviral therapy forat least 6 months AND is failing, or has recently failed therapy within the past 8 weeks
   AND
3. Documentation of current member's CD4 count [within past 30 days]
   AND

4. Confirmation that the member has been prescribed and will continue to take an optimized background antiretroviral regimen (OBR), containing at least one antiretroviral agent that demonstrates full viral sensitivity/susceptibility, in combination with Rukobia (fostemsavir) [Documentation of sensitivity/susceptibility must be submitted]

   AND
5. Viral resistance to at least ONE (1) agent from EACH of the (4) FOUR classes of HIV antiretroviral medications (as single agent products or combination products), unless contraindicated or clinically significant adverse effects are experienced. Documented resistance as measured by resistance testing, completed while member is currently on therapy or within 4 weeks if possible.
   1) Protease inhibitor (PI)
   2) Nucleoside reverse transcriptase inhibitor (NRTI)
   3) Non-nucleoside reverse transcriptase inhibitor (NNRTI)
   4) Integrase Inhibitors
   5) CCR5 antagonists
   6) Entry Inhibitors

   AND
6. Prescriber attestation that member is not concurrently taking any strong cytochrome P450 (CYP)3A inducers

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of Therapy: 12 months

QUANTITY:
Rukobia 600mg: 60 tablets per 30 days

PRESCRIBER REQUIREMENTS:
Prescribed by, or in consultation with, a board-certified infectious disease or HIV specialist. Consultation notes must be submitted for initial request and for continuation of treatment requests at least ONCE annually.

AGE RESTRICTIONS:
18 years of age and older

CONTINUATION OF THERAPY:
A. MULTI-DRUG RESISTANT HIV1 INFECTION:

1. Adherence to therapy at least 85% of the time as verified by Prescriber and member's medication fill history (review Rx history for compliance) NOTE: Therapy may be discontinued due to poor adherence upon recommendation of the Molina Medical Director when adherence < 85% has been demonstrated in at least two months during the course of therapy

   AND
2. Documentation of decreased viral load and increased CD4 count from baseline- indicating clinically significant disease response and improvement

   AND
3. Member continues to take an optimized background regimen (OBR) of antiretroviral therapy in combination with Rukobia (fostemsavir)

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Rukobia (fostemsavir) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Rukobia (fostemsavir) include: Hypersensitivity to fostemsavir or any component of the formulation; concomitant use of strong CYP3A inducers (e.g., enzalutamide, carbamazepine, phenytoin, rifampin, mitotane, St John's wort).

OTHER SPECIAL CONSIDERATIONS:
Use is not recommended in antiretroviral therapy-naïve patients. CD4 count, HIV RNA plasma levels, infusion-related reactions should be monitored. Virologic failure may be defined as not achieving a viral load of <200 copies/mL within 6 months (24 weeks) of initiating antiretroviral therapy. For individuals who were initially able to suppress their viral load, virologic failure is defined as a recurrence of viremia to >200 copies/mL on two consecutive measurements taken approximately one month apart

BACKGROUND:
No

APPENDIX:
None

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, member records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

REFERENCES:

1. Rukobia (fostemsavir) [prescribing information]. Research Triangle Park, NC:ViiV Healthcare; July 2020.
2. Kozal M, Aberg J, Pialoux G, et al. Fostemsavir in adults with multidrug-resistant HIV-1 infection. N Engl J Med. 2020;382(13):1232-1243. doi:10.1056/NEJMoa1902493
3. CDC. Estimated HIV incidence and prevalence in the United States, 2010-2015. HIV Surveillance Supplemental Report 2018;23(1).
4. US Department of Health and Human Services (HHS) Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available http://aidsinfo.nih.gov/contentfiles/lvguidelines/AdultandAdolescentGL.pdf.
5. US Department of Health and Human Services (HHS) Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission. Recommendations for the use of antiretroviral drugs in pregnant women with HIV infection and interventions to reduce perinatal HIV transmission in the United States. https://aidsinfo.nih.gov/contentfiles/lvguidelines/perinatalgl.pdf.